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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 09/889,807 | 03/01/2002 | Michael Almstetter | 56268 (41925) | 9002 |
| 21874 | 7590 | 04/06/2005 | EXAMINER | |
| EDWARDS & ANGELL, LLP | | | LIN, JERRY | |
| P.O. BOX 55874 | | | | |
| BOSTON, MA 02205 | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/889,807 | ALMSTETTER ET AL. |
| | Examiner | Art Unit |
| | Jerry Lin | 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 January 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3 and 5-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3 and 5-63 is/are rejected.
- 7) Claim(s) 5,14,42,43 and 53-57 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |



DETAILED ACTION

Applicants' arguments, filed January 20, 2005, have been fully considered and they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1-3 and 5-63 are pending.

Claims 1-3 and 5-63 are rejected.

Claims 5, 14, 42, 43, and 53-57 are objected to.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for depending on a cancelled claim.

Claims 42, 43, and 53-57 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claim 1, step 4 includes the evaluation of products based on biological, pharmacological or physicochemical criterion and the selection of a product. However, it is unclear how one ordinary skill in the art is to make selection of a product. Although the claim does recite the analysis and evaluation of products, the claim does not recite how or if the analysis or evaluation of the product has any bearing on the selection of a product. Thus one of ordinary skill in the art would not be enabled to use the invention as it is claimed.

Applicants has responded to this argument by amending their claim to include a biological, pharmacological or physicochemical criterion for the evaluation of a product and applicants have also pointed out representative examples in their specification on the evaluation process. However, as it is claimed, it is not clear how the evaluation

process has any bearing on the selection process. Interpreting step 4 broadly, there is still no criteria for the selection of the product.

Furthermore, claim 1 is interpreted broadly to encompass *in silico* methods. However, the specification only teaches physical methods of synthesis and *in vivo* testing of compounds. Thus the specification does not enable one of ordinary skill in the art to make or use the invention as claimed.

Applicants have responded to this rejection by stating that one of ordinary skill in the art would know how to execute their method *in silico*. They cite K. Buernator, et al. (Eds). "Structure-Base Ligan Design", Wiley (1998) as evidence of known methods of analysis and evaluation. The reference cited by the applicants only refer to the analysis and evaluation of a already created compound. It does not teach the computer modeling process of individual starting materials, nor does it teach how to model chemical reactions. Given the complexity of computer modeling compounds as well as modeling chemical reactions, for a practitioner to create an *in silico* version of the applicants' claimed method without any guidance or positive steps from the specification would cause undue experimentation. Computer modeling of chemical reactions is still on ongoing area of research and experimentation, especially in the case of complex proteins or other large biological molecules. The difficulties of coding such a complex program is further increase in the case of a combinatorial library of chemical where an astronomical number of products could be produced from just a few starting materials. Thus, without any guidance or positive steps from the specification, the specification

does not enable one of ordinary skill in the art for an *in silico* version of the claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

The term "suitable" in claims 1, 3 and 22 is a relative term which renders the claim indefinite. The term "suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 1 recites the limitation "the products" in line 7. There is insufficient antecedent basis for this limitation in the claim. The limitation of "the product" was not recited previously in the instant claim.

Step 3 and 4 recites a process of analyzing or evaluating the products for biological, pharmacological, or physicochemical criterion. It is unclear how step 3 is different from step 4 or why this process is repeated twice.

Regarding claim 6, it is unclear what is being evaluated. It appears that step 4 of the independent claim already evaluates all products. It is unclear why this step is repeated in an dependent claim.

Regarding claim 8, it is unclear what is being evaluated. It is unclear if the phrase "is if appropriate carried out" refers to the reaction or to the starting materials.

The term "appropriate" in claim 8, 34 is a relative term which renders the claim indefinite. The term "appropriate" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Regarding claim 10, 23, and 46 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "suitable" in claim 22 is a relative term which renders the claim indefinite. The term "suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Regarding claim 22, 24, and 37 the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 30, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05.

Regarding claim 44, the phrase “especially” renders the claim indefinite because it is unclear whether the limitation of “being a linear combination or polynome of those properties with “fuzzy” logic weightings” are part of the claimed invention. See MPEP § 2173.05(d).

The term "best" in claim 48 is a relative term which renders the claim indefinite. The term "best" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 15 is indefinite because it is unclear what is meant by “starting materials are provided with protecting groups.” One interpretation is that the starting materials are bound with protecting groups. Another interpretation is that the protecting groups are separate from the starting material but are in a mixture with the starting material.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 6:30-3:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
4/11/05

AC1631

JL